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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/615,736 07/13/00 HORROBIN

D P65773US0

EXAMINER

HM12/0810

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RESELEV E

ART UNIT

PAPER NUMBER

1623

DATE MAILED:

08/10/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

Office Action Summary

Application No.

09/615,736

Applicant(s)

Examiner

Group Art Unit

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- ☐ Responsive to communication(s) filed on _____.
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 111; 453 O.G. 213.

Disposition of Claims

- ☒ Claim(s) 1-15 is/are pending in the application.
- Of the above claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 1-15 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
 - ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.
 - ☐ received in Application No. (Series Code/Serial Number) _____.
 - ☐ received in this national stage application from the International Bureau (PCT Rule 1.7.2(a)).

*Certified copies not received: _____

Attachment(s)

- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 4
- ☐ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Interview Summary, PTO-413
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Other _____

Office Action Summary

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Claim 15 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claim 15 is directed to a formulation for use in therapy of any illness, any cardiovascular disorder or cerebrovascular disorder, any form of diabetes or pre-diabetes, any form of psychiatric disorder, any form of neurological or neurodegenerative disorder, any form of kidney disorder, any form of inflammatory or immunological disorder, any form of eye or hearing disorder, any form of obesity and any form of cancer. However, the specification fails to present any evidence that the claimed formulation is useful in therapy and prevention of all the disorders listed in claim 15. Since there is no known formulation that is useful in the therapy and prevention of all illnesses, there is a good reason to doubt that the claimed formulation is useful in therapy and prevention of all the illnesses set forth in claim 15.

Claims 1-15 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methyltetrahydrofolate, does not reasonably provide enablement for a compound related to folic acid with similar biological activity. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. The only compound disclosed by the specification that is related to folic acid is methyltetrahydrofolate. It would take an undue amount of experimentation to determine which other compounds that are related to folic acid will be useful in the instant invention.

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Claims 1-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 15 are substantial duplicates.

Claims 1-3 are indefinite in that the same improperly depend from FIG. 1.

The terminology "selected from" (claims 1-3 and 14) is an improper markush terminology. Such terminology as "selected from the group consisting of" can be used to overcome the rejection.

Regarding claims 10-11, the phrase "preferably" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Regarding claim 15, the phrase "including" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-15 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over the European Patent No. 0,305,097, the European Patent No. 0,198,804 or WO 99/03482.

The European Patent'097 discloses a formulation comprising one or more of the essential fatty acids and vitamins B6, B12, C and E (see, for example, page 12, claims 6 and 10).

The European Patent'804 discloses a formulation comprising essential fatty acids and vitamins B6 and E (page 4).

The Wo Patent discloses a formulation comprising essential fatty acids, folic acid and vitamins B6, B12 and E.

The claimed compositions are anticipated by the European patents and by the WO Patent.

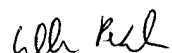
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In addition, if there are any differences between the claimed compositions and the prior art compositions, the differences would appear to be minor in nature and the claimed compositions, which fall within the scope of the prior art disclosure, would have been prima facie obvious from the said prior art disclosure to a person having ordinary skill in the art at the time the instant invention was made.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elli Peshev whose telephone number is (703) 308-4616. by he examiner can normally be reached on weekdays from 9.30 a.m. to 6.00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Geist, can be reached on (703) 308-1701. by he fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.


ELLI PESELEV
PRIMARY EXAMINER
GROUP 1200